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10/531,546	10/21/2005	William R. Freeman	1034123-000153	3894

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
09/24/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/531,546	FREEMAN, WILLIAM R.	
	Examiner	Art Unit	
	GiGi Huang	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *19-23 and 25-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/15/2005 and 10/21/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-18 and 24, in the reply filed on August 27, 2007 is acknowledged. The traversal is on the ground(s) that the first element of restriction between inventions are that they are to be independent or distinct per MPEP 806.04 and 806.05 and the second element is serious burden, of which the Applicants asserts that there is no search burden and that the Groups I and II are related and share the same technical feature. This is not found persuasive because the instant case is a national stage application submitted under 35 U.S.C. 371, the Unity of Invention practice in MPEP 1850 and MPEP 1893.03(d) was followed, not restriction practice. Thus, the criteria for burden stated in MPEP 803 for national applications filed under 35 U.S. C. 111(a) does not apply MPEP 801. Secondary, the inventive step must be present and shared by all the claims and not solely to Group II and I. As stated in the previous action, Groups I-IV did not relate to a single inventive concept. The technical feature linking the claims is the method of using a photosensitizer with a photo activating light present in the prior art (Strong et al.).

The requirement is still deemed proper and is therefore made FINAL.

Status of Application

2. Applicant has elected Group I in response to restriction requirement for the examination.

Due to restriction, based on election of Group I, claims 19-23 and 25-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Claims 1-18 and 24 are present for examination at this time.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Regarding claim 15, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8, 10-12, 14, 16-17, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sullivan (Jacksonville Medicine).

Sullivan teaches the method of treating choroidal neovascularization caused by age-related macular degeneration. The method utilized fluorescein angiograms to determine the presence, location, and extent of the choroidal neovascularization by

injection of a dye into a vein and multiple photographs of the retina. Treatment followed with the use of photodynamic therapy utilizing verteporfin coupled with low-density lipoprotein and injected intravenously. A non-thermal laser light was then used to activate the verteporfin at the area of neovascularization. The wavelength used was 689 nm, corresponding to the absorption peak of the verteporfin dye. The resulted in thrombosis and occlusion of the abnormal vessel (Pages 396-398).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

8. Claims 1-8, 10-12, 14, 16-17, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. (U.S. Pat. No. 5798349).

Levy et al. teaches a method of photodynamic therapy for unwanted neovasculature in the eye specifically in Age-related macular degeneration. Fundus photography, histologic examination, and fluorescein angiography were used to observe and identify the choroidal neovasularization. A green porphyrin, BPD-MA (verteporfin), was combined with lipoproteins, and injected intravenously in a leg vein. The eyes were then irradiated with a laser at 692 nm to treat the areas of choroidal neovascularization. Subsequent angiography was used to show the closure of the vasculature (Abstract, Col.1, lines 18-48, 55-63, Col. 2, lines 13-32, 39-52, Col. 3, lines 32-40, 45-59, Col. 6, lines 1-36, Col. 8, lines 26-45, Examples 1-2, Col. 9, Example 3 and 4, Col. 11 Table 5).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) as applied to claims 1-8, 10-12, 14, 16-17, and 24 above, and in view of Levy et al. (U.S. Pat. No. 4920143).

The teachings of Sullivan (Jacksonville Medicine) are discussed above.

Sullivan does not expressly teach the topical application of the photosensitizer.

Levy et al. (U.S. Pat. No. 4920143 teaches that the photosensitizing compounds can be administered in formulations well known in the art for systemic or topical use (Col. 10, lines 65-68, Col. 11, lines 1-33).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try topical administration, as suggested by Levy, and produce the instant invention. It would have obvious to try topical administration as it would be another method of administration if adequate intravenous lines would not be available such as collapsed veins.

One of ordinary skill in the art would have been motivated to do this because topical administration does not require additional equipment such as IV drips and saline flushes, simplifying the procedure and cost to the practitioner.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

All the critical elements are taught by the cited reference and thus the claims are rejected.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) as applied to claims 1-8, 10-12, 14, 16-17, and 24 above, and in view of Levy et al. (U.S. Pat. No. 4920143).

The teachings of Levy et al. (U.S. Pat. No. 5798349) are discussed above.

Levy et al. (U.S. Pat. No. 5798349) does not expressly teach the topical application of the photosensitizer.

Levy et al. (U.S. Pat. No. 4920143), which is fully incorporated by reference in Levy et al. (U.S. Pat. No. 5798349), teaches that the photosensitizing compounds can be administered for systemic or topical use in formulations well know in the art (Col. 10, lines 65-68, Col. 11, lines 1-33).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try topical administration, as suggested by Levy, and

produce the instant invention. It would have obvious to try topical administration as it would be another method of administration if adequate intravenous lines would not be available such as collapsed veins.

One of ordinary skill in the art would have been motivated to do this because topical administration does not require additional equipment such as IV drips and saline flushes, simplifying the procedure and cost to the practitioner.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

All the critical elements are taught by the cited reference and thus the claims are rejected.

12. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) as applied to claims 1-8, 10-12, 14, 16-17, and 24 above, and in view of Roach (EyeNet Magazine March 2001).

The teachings of Sullivan are discussed above. Sullivan also teaches that laser photocoagulation treatment is also available for the condition but less than 20% of patients meet the eligibility criteria.

Sullivan does not expressly teach the use of high speed scanning laser ophthalmoscope or the use of indocyanine green.

Roach teaches that new and sophisticated imaging systems are improving the results of feeder vessel treatment in macular degeneration. Essentially, it is easier to treat a blood vessel you can see than one you can't.

Roach teaches that real-time digital imaging systems for high-speed indocyanine green angiography (HSICG) coupled with a scanning laser ophthalmoscope can produce real time imaging where the indocyanine green dye used can be seen moving through the choroidal vessels.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize high-speed indocyanine green angiography, as suggested by Roach, and produce the instant invention. While described for laser photocoagulation treatment, it would have obvious to one of skill in the art that the imaging technique would also be invaluable in photodynamic therapy to improve the accuracy and images available to the practitioner to diagnosis and perform the therapy effectively.

One of ordinary skill in the art would have been motivated to do this because Roach teaches that because the system operates in real time, it is possible to immediately treat an area as it is identified. The system allows the practitioner to increase number of vessels to be treated since it increases the number of vessel you can see.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

All the critical elements are taught by the cited reference and thus the claims are rejected.

13. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) as applied to claims 1-8, 10-12, 14, 16-17, and 24 above, and in view of Roach (EyeNet Magazine March 2001).

The teachings of Levy are discussed above. Levy also teaches that laser photocoagulation treatment is also available for the condition due to the side effects, scarring, and level of prognosis, strategies such as photodynamic therapy are desirable since there is greater selective closure of the blood vessels.

Levy does not expressly teach the use of high speed scanning laser ophthalmoscope or the use of indocyanine green.

Roach teaches that new and sophisticated imaging systems are improving the results of feeder vessel treatment in macular degeneration. Essentially, it is easier to treat a blood vessel you can see than one you can't. Roach teaches that real-time

digital imaging systems for high-speed indocyanine green angiography (HSICG) coupled with a scanning laser ophthalmoscope can produce real time imaging where the indocyanine green dye used can be seen moving through the choroidal vessels.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize high-speed indocyanine green angiography, as suggested by Roach, and produce the instant invention. While described for laser photocoagulation treatment, it would have obvious to one of skill in the art that the imaging technique would also be invaluable in photodynamic therapy to improve the accuracy and images available to the practitioner to diagnosis and perform the therapy effectively.

One of ordinary skill in the art would have been motivated to do this because Roach teaches that because the system operates in real time, it is possible to immediately treat an area as it is identified. The system also allows the practitioner to increase number of vessels to be treated since it increases the number of vessel you can see.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the

time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

All the critical elements are taught by the cited reference and thus the claims are rejected.

14. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (Jacksonville Medicine) as applied to claims 1-8, 10-12, 14, 16-17, and 24 above, and in view of LumaCare (http://lumacare.com/EMEA/pr3.html).

The teachings of Sullivan are discussed above. Sullivan teaches the use of coherent light (lasers) in photodynamic therapy.

Sullivan does not expressly teach the use of non-coherent light.

LumaCare teaches the use, availability, and benefit of the LumaCare LC-122 a non-coherent light source for affordable photodynamic therapy activation. The product is compact, lightweight, portable, safer, easier to use, and more affordable to implement than lasers. It can generate light frequencies from 400-800nm for a wide range of photodynamic therapy (PDT) and requires minimal maintenance.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use non-coherent light, as suggested by LumaCare, and produce the instant invention. As taught by LumaCare, traditional light sources for PDT are lasers that are expensive and most are only able to produce a narrow range of light frequencies. The LumaCare is more affordable with greater range of frequencies for various PDT treatments, portable, requires minimal training of staff, and as a result, very cost effective.

One of ordinary skill in the art would have been motivated to do this because not only is LumaCare affordable, it can be used in multiple treatment rooms increasing the number of patients that can be treated. This decreases the overhead, increases efficiency, and increases productivity of the practitioner thereby providing more income, a very strong motivation.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

All the critical elements are taught by the cited reference and thus the claims are rejected.

15. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U.S. Pat. No. 5798349) as applied to claims 1-8, 10-12, 14, 16-17, and 24 above, and in view of LumaCare (Press release - http://lumacare.com/EMEA/pr3.html).

The teachings of Levy et al. are discussed above. Levy teaches the use of coherent light (lasers) in photodynamic therapy.

Levy does not expressly teach the use of non-coherent light.

LumaCare teaches the use, availability, and benefit of the LumaCare LC-122 a non-coherent light source for affordable photodynamic therapy activation. The product is compact, lightweight, portable, safer, easier to use, and more affordable to implement than lasers. It can generate light frequencies from 400-800nm for a wide range of photodynamic therapy (PDT) and requires minimal maintenance.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use non-coherent light, as suggested by LumaCare, and produce the instant invention. As taught by LumaCare, traditional light sources for PDT are lasers that are expensive and most are only able to produce a narrow range of light frequencies. The LumaCare is more affordable with greater range of frequencies for various PDT treatments, portable, requires minimal training of staff, and as a result, very cost effective.

One of ordinary skill in the art would have been motivated to do this because not only is LumaCare affordable, it can be used in multiple treatment rooms increasing the number of patients that can be treated. This decreases the overhead, increases efficiency, and increases productivity of the practitioner thereby providing more income, a very strong motivation.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore,

the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

All the critical elements are taught by the cited reference and thus the claims are rejected.

Conclusion

16. Claims 1-18 and 24 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER